

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

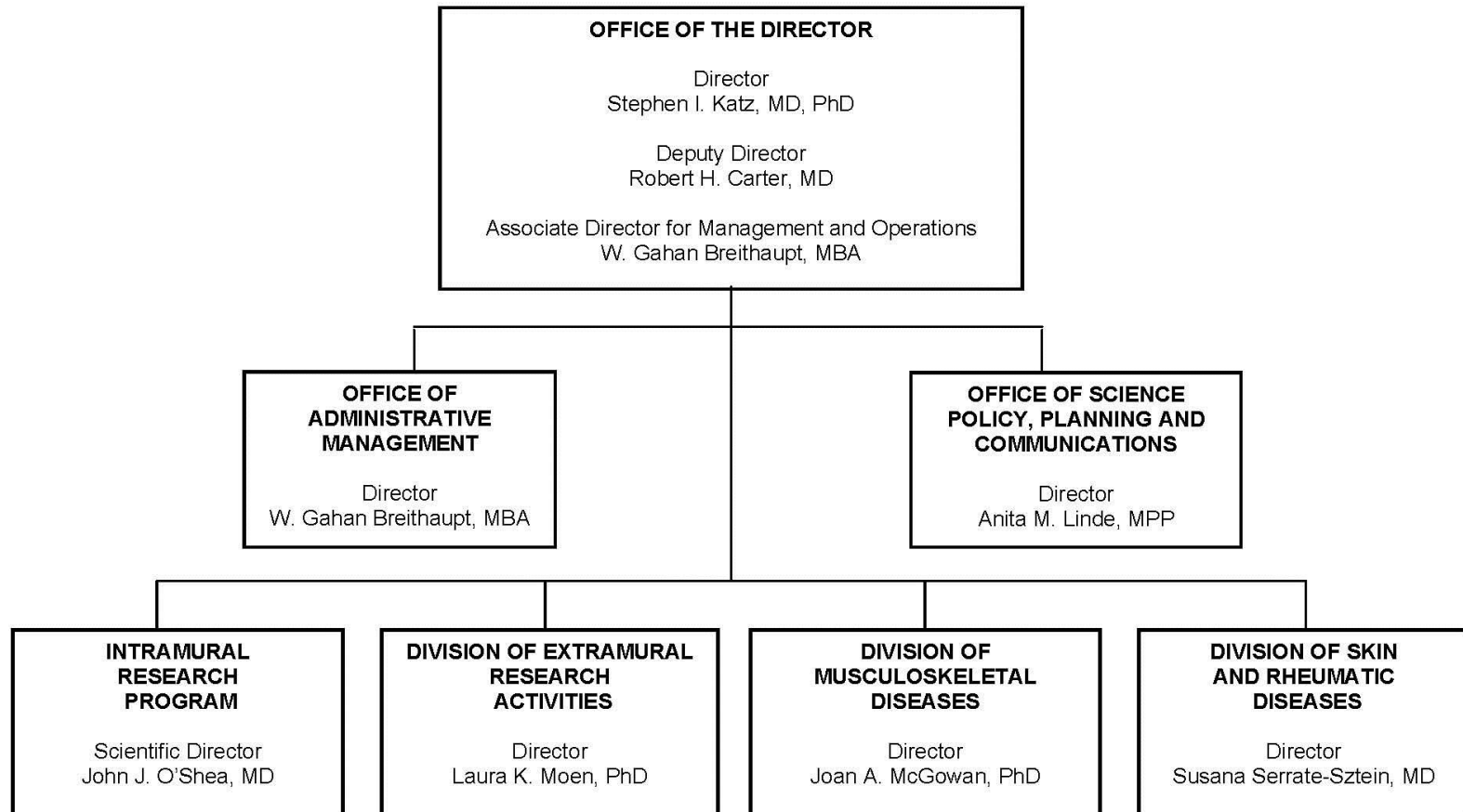
<u>FY 2017 Budget</u>	<u>Page No.</u>
Organization Chart.....	2
Appropriation Language	3
Amounts Available for Obligation.....	4
Budget Mechanism Table	5
Major Changes in Budget Request	6
Summary of Changes	7
Budget Graphs	9
Budget Authority by Activity	10
Authorizing Legislation	11
Appropriations History	12
Justification of Budget Request	13
Budget Authority by Object Class	23
Salaries and Expenses	24
Detail of Full-Time Equivalent Employment (FTE)	25
Detail of Positions	26

NOTE: The FY 2016 Enacted funding amounts cited throughout this chapter reflect the effects of OAR HIV/AIDS Transfers.

NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Organizational Structure



NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis and Musculoskeletal and Skin Diseases

For carrying out section 301 and title IV of the PHS Act with respect to arthritis and musculoskeletal and skin diseases, [~~\$542,141,000~~]*\$532,753,000*.

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Amounts Available for Obligation¹
(Dollars in Thousands)

Source of Funding	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
Appropriation	\$521,665	\$542,141	\$541,662
Mandatory Appropriation: (non-add)			
<i>Type 1 Diabetes</i>	(0)	(0)	(0)
<i>Other Mandatory financing</i>	(0)	(0)	(8,909)
Rescission	0	0	0
Sequestration	0	0	0
FY 2015 First Secretary's Transfer	0	0	0
FY 2015 Second Secretary's Transfer	0	0	0
Subtotal, adjusted appropriation	\$521,665	\$542,141	\$541,662
OAR HIV/AIDS Transfers	-137	-479	0
National Children's Study Transfers	0	0	0
Subtotal, adjusted budget authority	\$521,528	\$541,662	\$541,662
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$521,528	\$541,662	\$541,662
Unobligated balance lapsing	-48	0	0
Total obligations	\$521,480	\$541,662	\$541,662

¹ Excludes the following amounts for reimbursable activities carried out by this account:
FY 2015 - \$1,583 FY 2016 - \$1,458 FY 2017 - \$1,472

**NATIONAL INSTITUTES OF HEALTH
FY 2017 Congressional Justification
NIAMS**

Budget Mechanism - Total¹

(Dollars in Thousands)

MECHANISM	FY 2015 Actual		FY 2016 Enacted		FY 2017 President's Budget ³		FY 2017 +/- FY 2016	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<u>Research Projects:</u>								
Noncompeting	666	\$233,630	692	\$253,260	688	\$256,940	-4	\$3,680
Administrative Supplements	(28)	2,444	(25)	2,200	(25)	2,200		
Competing:								
Renewal	55	23,912	66	22,072	62	20,827	-4	-1,245
New	218	68,176	189	62,930	179	59,381	-10	-3,549
Supplements	6	841	2	776	2	732		-44
Subtotal, Competing	279	\$92,928	257	\$85,778	243	\$80,940	-14	-\$4,838
Subtotal, RPGs	945	\$329,001	949	\$341,238	931	\$340,080	-18	-\$1,158
SBIR/STTR	43	14,280	47	15,753	50	16,671	3	918
Research Project Grants	988	\$343,281	996	\$356,991	981	\$356,751	-15	-\$240
<u>Research Centers:</u>								
Specialized/Comprehensive	42	\$43,091	42	\$43,470	42	\$43,470		
Clinical Research								
Biotechnology								
Comparative Medicine		29		29		29		
Research Centers in Minority Institutions								
Research Centers	42	\$43,120	42	\$43,499	42	\$43,499		
<u>Other Research:</u>								
Research Careers	144	\$18,118	144	\$20,672	144	\$20,672		
Cancer Education								
Cooperative Clinical Research								
Biomedical Research Support								
Minority Biomedical Research Support		195		195		195		
Other	25	2,919	25	2,919	25	2,919		
Other Research	169	\$21,232	169	\$23,786	169	\$23,786		
Total Research Grants	1,199	\$407,633	1,207	\$424,276	1,192	\$424,036	-15	-\$240
<u>Ruth L. Kirchstein Training Awards:</u>	<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>	
Individual Awards	64	\$3,006	65	\$3,054	66	\$3,103	1	\$49
Institutional Awards	222	11,726	225	11,914	229	12,105	4	191
Total Research Training	286	\$14,732	290	\$14,968	295	\$15,208	5	\$240
Research & Develop. Contracts (SBIR/STTR) (non-add) ²	45	\$16,211 (120)	45	\$16,211 (124)	45	\$16,211 (129)		(5)
Intramural Research	134	\$54,168	135	\$56,294	135	\$56,294		
Res. Management & Support Res. Management & Support (SBIR Admin) (non-add) ²	103	28,784	104	29,913	104	29,913		
Office of the Director - Appropriation ²								
Office of the Director - Other								
ORIP/SEPA (non-add) ²								
Common Fund (non-add) ²								
Buildings and Facilities								
Appropriation								
Type 1 Diabetes								
Program Evaluation Financing								
Cancer Initiative Mandatory Financing								
Other Mandatory Financing						-8,909		-8,909
Subtotal, Labor/HHS Budget Authority		\$521,528		\$541,662		\$532,753		-\$8,909
Interior Appropriation for Superfund Res.								
Total, NIH Discretionary B.A.		\$521,528		\$541,662		\$532,753		-\$8,909
Type 1 Diabetes								
Proposed Law Funding								
Cancer Initiative Mandatory Financing								
Other Mandatory Financing						8,909		8,909
Total, NIH Budget Authority		\$521,528		\$541,662		\$541,662		
Program Evaluation Financing								
Total, Program Level		\$521,528		\$541,662		\$541,662		

¹ All Subtotal and Total numbers may not add due to rounding.

² All numbers in italics and brackets are non-add.

³ Includes mandatory financing.

Major Changes in the Fiscal Year 2017 President's Budget Request

Major changes by budget mechanism and / or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail and these highlights will not sum to the total change for the FY 2017 President's Budget for NIAMS, which is flat over the FY 2016 Enacted level, for a total of \$541.662 million.

Research Project Grants (-\$0.240 million; total \$356.751 million):

NIAMS will support a total of 981 Research Project Grant (RPG) awards in FY 2017. Noncompeting awards will decrease by 4 awards but increase by \$3.680 million. Competing RPGs will decrease by 14 awards and \$4.838 million. NIAMS continues to place a priority on support to new investigators.

Research Training (+\$0.240 million; total \$15.208 million):

NIAMS will support 295 pre- and postdoctoral trainees in full-time training positions, an increase of 5 positions more than the FY 2016 Enacted Level. Support for NRSA training mechanism will be increased by \$0.240 million amount to cover the cost of increased stipends.

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Summary of Changes

(Dollars in Thousands)

FY 2016 Enacted				\$541,662
FY 2017 President's Budget				\$541,662
Net change				\$0
CHANGES	FY 2017 President's Budget'		Change from FY 2016	
	FTEs	Budget Authority	FTEs	Budget Authority
<u>A. Built-in:</u>				
<u>1. Intramural Research:</u>				
a. Annualization of January 2016 pay increase & benefits		\$20,684		\$63
b. January FY 2017 pay increase & benefits		20,684		124
c. Two less days of pay		20,684		-160
d. Differences attributable to change in FTE		20,684		0
e. Payment for centrally furnished services		10,085		340
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		25,525		-550
Subtotal				-\$183
<u>2. Research Management and Support:</u>				
a. Annualization of January 2016 pay increase & benefits		\$16,726		\$51
b. January FY 2017 pay increase & benefits		16,726		99
c. Two less days of pay		16,726		-129
d. Differences attributable to change in FTE		16,726		0
e. Payment for centrally furnished services		3,899		95
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		9,288		-266
Subtotal				-\$150
Subtotal, Built-in				-\$333

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Summary of Changes

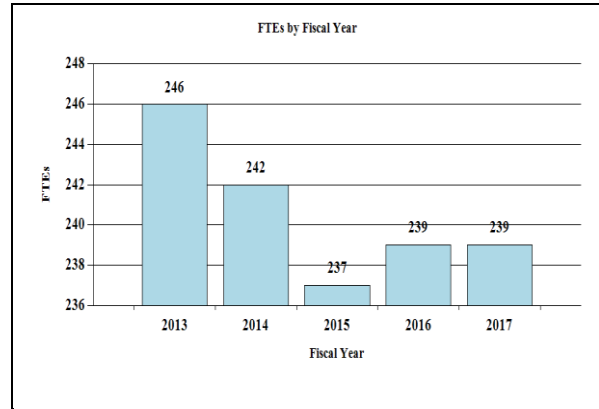
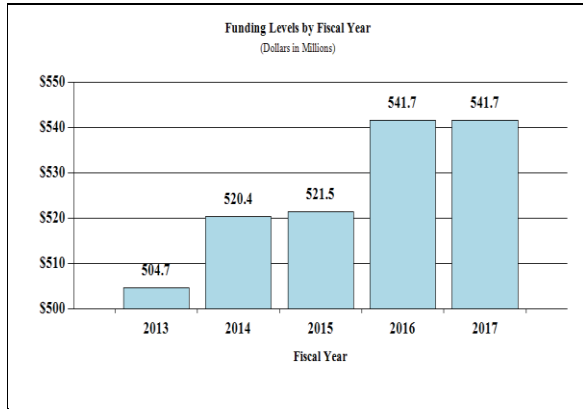
(Dollars in Thousands)

FY 2016 Enacted		\$541,662	
FY 2017 President's Budget		\$541,662	
Net change		\$0	
CHANGES	FY 2017 President's Budget¹		Change from FY 2016
	No.	Amount	No. Amount
B. Program:			
1. Research Project Grants:			
a. Noncompeting	688	\$259,140	-4 \$3,680
b. Competing	243	80,940	-14 -4,838
c. SBIR/STTR	50	16,671	3 918
Subtotal, RPGs	981	\$356,751	-15 -\$240
2. Research Centers	42	\$43,499	0 \$0
3. Other Research	169	23,786	0 0
4. Research Training	295	15,208	5 240
5. Research and development contracts	45	16,211	0 0
Subtotal, Extramural		\$455,455	\$0
6. Intramural Research			
	<u>FTEs</u>		<u>FTEs</u>
	135	\$56,294	0 \$183
7. Research Management and Support	104	29,913	0 150
8. Construction		0	0
9. Buildings and Facilities		0	0
Subtotal, Program	239	\$541,662	0 \$333
Total changes			\$0

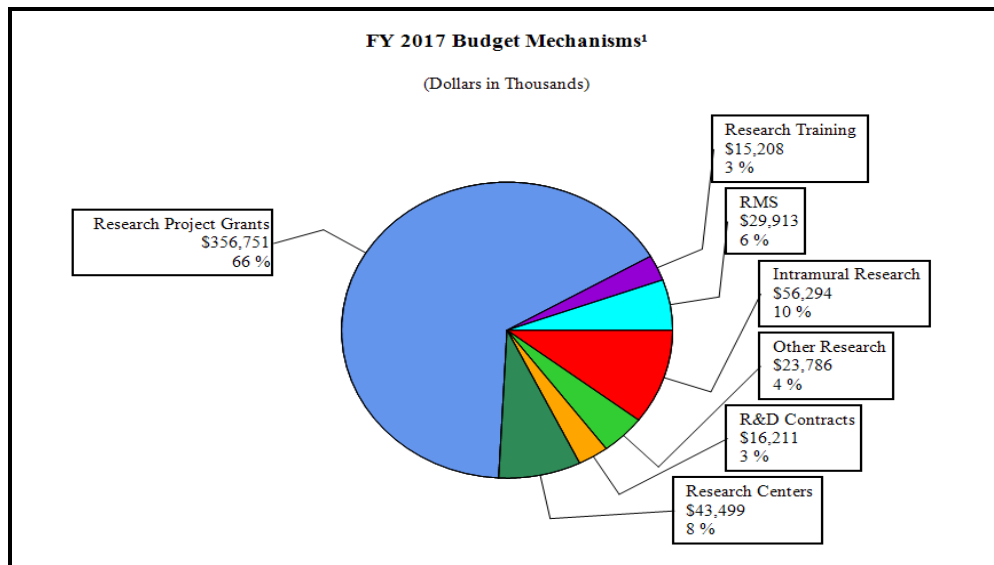
¹ Includes mandatory financing.

Fiscal Year 2017 Budget Graphs

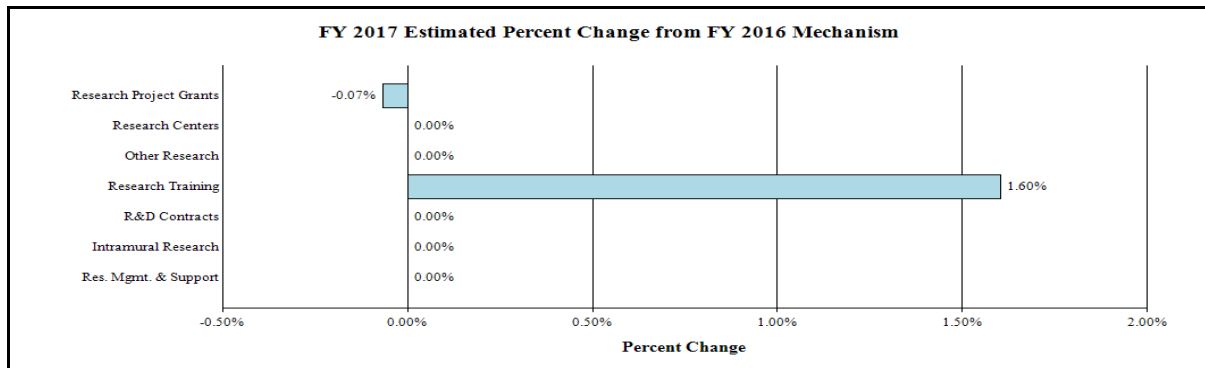
History of Budget Authority and FTEs:



Distribution by Mechanism:



Change by Selected Mechanism:



NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Budget Authority by Activity¹
(Dollars in Thousands)

	FY 2015 Actual		FY 2016 Enacted		FY 2017 President's Budget ²		FY 2017 +/- FY2016	
<u>Extramural Research</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>
<u>Detail</u>								
Arthritis and Rheumatic Diseases		\$99,231		\$103,051		\$103,051		\$0
Musculoskeletal Biology and Diseases		139,498		144,862		144,862		0
Bone Biology and Diseases		62,105		64,496		64,496		0
Muscle Biology and Diseases		65,347		67,863		67,863		0
Skin Biology and Diseases		72,396		75,183		75,183		0
Subtotal, Extramural		\$438,577		\$455,455		\$455,455		\$0
Intramural Research	134	\$54,168	135	\$56,294	135	\$56,294	0	\$0
Research Management & Support	103	\$28,784	104	\$29,913	104	\$29,913	0	\$0
TOTAL	237	\$521,528	239	\$541,662	239	\$541,662	0	\$0

¹ Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

² Includes mandatory financing.

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2016 Amount Authorized	FY 2016 Enacted	2017 Amount Authorized	FY 2017 President's Budget ¹
Research and Investigation	Section 301	42§241	Indefinite	\$541,662,000	Indefinite	\$532,753,000
National Institute of Arthritis and Musculoskeletal and Skin Diseases	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				\$541,662,000		\$532,753,000

¹Excludes mandatory financing.

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2007	\$504,533,000	\$504,533,000	\$508,585,000	\$508,240,000
Rescission				\$0
2008	\$508,082,000	\$516,044,000	\$519,810,000	\$517,629,000
Rescission				\$9,043,000
Supplemental				\$2,075,000
2009	\$509,080,000	\$526,583,000	\$523,246,000	\$524,872,000
Rescission				\$0
2010	\$530,825,000	\$543,621,000	\$533,831,000	\$539,082,000
Rescission				\$0
2011	\$555,715,000		\$554,846,000	\$539,082,000
Rescission				\$4,733,461
2012	\$547,891,000	\$547,891,000	\$528,332,000	\$536,801,000
Rescission				\$1,014,454
2013	\$535,610,000		\$537,233,000	\$535,786,446
Rescission				\$1,071,573
Sequestration				(\$26,892,795)
2014	\$540,993,000		\$537,398,000	\$520,053,000
Rescission				\$0
2015	\$520,189,000			\$521,665,000
Rescission				\$0
2016	\$533,232,000	\$528,137,000	\$544,274,000	\$542,141,000
Rescission				\$0
2017 ¹	\$541,662,000			

¹ Includes mandatory financing.

Justification of Budget Request

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended.

Budget Authority (BA):

	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
BA	\$521,528,000	\$541,662,000	\$541,662,000	+\$0
FTE	237	239	239	+2

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Director's Overview

As the primary Federal agency for supporting medical research on diseases of the bones, joints, muscles, and skin, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) touches the lives of nearly every American. Arthritis limits the activities of approximately 22.7 million adults in the United States each year; medical care and lost wages attributable to musculoskeletal conditions cost Americans an estimated \$874 billion annually; and skin conditions such as eczema and psoriasis affect more than 12 percent of people worldwide.¹ NIAMS is working to enhance health, lengthen life, and reduce illness and disability by supporting basic and translational research that will impact clinical practice, training the next generation of bone, joint, muscle, and skin scientists, and disseminating the findings and related health information from the studies it supports to all Americans. The activities described below highlight NIAMS' many efforts to advance public health.

Much of the NIAMS budget supports research into the fundamental biological processes that are responsible for making and maintaining healthy bones, joints, muscles, skin, and immune responses. The long-term goal of this work is to develop ways to allow people to live longer, healthier lives. For example, researchers used what was known about the fluid surrounding joint areas to bioengineer a molecule that links key lubricating elements together. The new molecular complex appears to minimize friction within the knee joint and has promise for slowing the degeneration of cartilage tissue that occurs in knee osteoarthritis. As another example, intramural researchers studying how the packaging of genetic material in cells may contribute to disease discovered that areas involved in gene expression in immune cells overlap with genomic regions that have previously

¹ Barbour KE, et al. Prevalence of doctor-diagnosed arthritis and arthritis-attributable activity limitation-United States, 2010-2012. MMWR 2013;62 (44):869-873
U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, Medical Expenditures Panel Survey, 1996-2011, as cited in <http://www.boneandjointburden.org/docs/T10015.14.pdf>, accessed October 1, 2015

Vos T, et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet. 2012 Dec 15;380(9859):2163-96. PMID: 2324560

been linked to autoimmune diseases, and that gene activity in these regions changes significantly in response to drugs for autoimmune diseases. Future research efforts will explore how changes to these DNA regions can lead to disease, with the goal of uncovering additional treatment targets. In addition, researchers exploring large volumes of genetic and gene-expression data have made an unexpected discovery of a gene that affects bone density and fracture risk. The results from this study, which involved data from more than half-a-million volunteers, provide insights into the genetics underlying osteoporosis and may lead to new ways to prevent bone loss and fractures. The study also exemplifies the power of “big data” from large cohorts to uncover genetic and other information that will be needed to achieve the goal of precision medicine tailored to individual patients.

In some cases, researchers require only a few hundred volunteers to gain insights into how disease develops, what types of molecules might be effective drugs, or how a person is responding to a treatment. NIAMS-funded investigators who compared proteins in blood samples from boys who have Duchenne muscular dystrophy and boys who do not have the disease found differences in the concentrations of almost four dozen proteins. Some proteins were more abundant than normal in younger patients, but their levels decreased as the boys got older, suggesting that the molecules were involved in early stages of muscle deterioration and might be appropriate targets for therapy development. The lack of biomarkers for monitoring disease progression and response to therapy has been a major impediment to advancing new treatments for Duchenne muscular dystrophy, and the proteins identified from this study may fill that gap. Other researchers also are using biomarkers to develop tests for monitoring a person’s response to treatment. One group looked at whether markers of scleroderma-related skin damage could be used to assess if an experimental compound was benefiting patients. The results strongly indicated that the markers could be the basis for a useful test and showed that the compound blocked the molecular events leading to scar formation. This is particularly exciting because the discovery of a new way to prevent scarring also may provide a major advance for organ dysfunction seen in lung, liver, and kidney fibrosis and other conditions characterized by the accumulation of scar tissue.

Like scarring, pain and disability have profound effects on patients’ lives. We know that when people with knee osteoarthritis lose weight due to changes in diet and exercise, they feel better and move more easily. However, a recent study showed that weight loss does not correlate with any structural improvements in the joint. While the connection between weight loss and reduction of symptoms clearly means that improved diet and exercise should continue to be important components of osteoarthritis management, the lack of a connection between clinical and structural changes cautions against requiring clinical trials to show improvements in joint structure, as well as in pain and function, before a treatment can be considered effective. In FY 2017, NIAMS will continue to support research into strategies that will allow health care providers and researchers to assess how interventions affect people’s lives through ongoing support of an NIH-wide research consortium to assess the health of children with a variety of chronic diseases and conditions in clinical research and care settings. The main, long-term goal of the Consortium is to conduct robust clinical validation studies of child patient-reported outcomes, and to examine the impact of environmental stressors (including socioeconomic aspects) on children’s symptoms and quality of life. The consortium will use pediatric self-report and parent proxy instruments developed through the NIH Common Fund’s PROMIS® –

or Patient Reported Outcomes Measurement Information System – initiative, which NIAMS led for many years.

Part of NIAMS' FY 2017 planning process entails an examination of the types of support that clinical researchers require as they move their ideas from conceptualization, to full implementation, to improved clinical practice and patient care. NIAMS also is revisiting its approach for identifying and funding clinical trials that are as timely and informative as possible. A separate FY 2017 effort to support clinician-scientists at the vulnerable transition period from a mentored to independent career is a new, small grant program specifically for clinical researchers who are in the last years of their career development awards. Also, in response to recommendations from a working group convened to ascertain whether the Centers program was continuing to meet the needs of the scientific community, NIAMS is reconfiguring its Multidisciplinary Clinical Research Centers (MCRC), which have existed since 2001 to promote clinical, epidemiological, and health services research. The new program, called Core Centers for Clinical Research, will capitalize on the strengths of the MCRC Methodology Cores and their important roles in fostering clinical research and collaborations while providing investigators with greater flexibility in the scope of work and structure of their formal interactions. Together, these stewardship efforts will enhance the impact of NIAMS-funded clinical research programs and help ensure the most robust outcomes.

Overall Budget Policy:

The FY 2017 President's Budget request for NIAMS is \$541.662 million, a flat level over the FY 2016 Enacted level.

Program Descriptions and Accomplishments

Arthritis and Rheumatic Diseases: This program advances high-quality basic, translational, and clinical biomedical and biopsychosocial research to treat, cure, and prevent arthritis and autoimmune diseases. It supports the application of new insights in the fields of genetics, genomics, proteomics, immunology, and imaging to understand how the immune system interacts with various tissues in normal and pathological conditions, and to ensure a continuous supply of new targets on which therapies can be based. NIAMS research into the natural history of diseases such as lupus is helping patients plan for their futures and understand how the disease may affect them. When investigators launched the multi-center study known as PROMISSE (Predictors of Pregnancy Outcome: bioMarkers In antiphospholipid antibody Syndrome and Systemic lupus Erythematosus) in 2003, no one knew what patient characteristics or disease signs or symptoms were associated with poor pregnancy outcomes. The study has shown that most women who have lupus can expect a good pregnancy outcome if their disease is inactive. The investigators also identified some molecules in the women's blood that indicate a higher risk for serious pregnancy complications. These findings will enable providers to personalize assessment, counseling, and treatment for women with lupus. This and other advances have set the foundation for research into many aspects of lupus, a broad range of which are outlined in the 2015 Action Plan for Lupus Research (see Program Portrait).

Portrait of a Program: An Action Plan for Lupus Research

FY 2016 level: \$42.0 million

FY 2017 level: \$42.0 million

Change: \$0.0 million

Systemic lupus erythematosus (SLE, or lupus) is an inflammatory, disabling, and sometimes deadly autoimmune disease that affects multiple organ systems. Researchers from the Centers for Disease Control and Prevention (CDC) estimate that at least 322,000 Americans definitely or probably have lupus. Recent independent surveys have suggested a prevalence as high as 1.5 million.² Women with the disease outnumber men nine to one. Lupus often strikes women in their early working and childbearing years, interfering with the ability to work, have or raise a family, or in some cases even care for themselves. Sixty years ago, 50 percent of people who had lupus were alive five years after being diagnosed. Today, thanks to advances brought about by research on the mechanisms of disease and aggressive therapy, survival rates have increased to 97 percent at five years and 90 percent at ten years. The transformation from a disease with high mortality to a chronic disease means an increased need for therapies to prevent or manage long-term manifestations of the disease. The search for better treatments with fewer side effects requires a cross-disciplinary approach, and NIAMS has led the collaboration of multiple NIH ICs, as well as other Federal agencies and voluntary organizations, through the Lupus Federal Working Group and the development of a plan to identify research opportunities and needs. The Action Plan for Lupus Research was released in late fall of 2015 in response to a request from the Congressional Lupus Caucus. It highlights opportunities to increase the field's understanding of lupus at the molecular, individual, and population levels, which should allow the translation of knowledge into safer and more effective treatments and, eventually, into cures. The Plan is intended to inform all lupus-related organizations, and to serve as a guide for investigators as they develop their own approaches to address the numerous scientific opportunities in lupus.

Budget Policy:

The FY 2017 budget estimate for this program is \$103.051 million, the same as the FY 2016 Enacted level. Program plans for FY 2017 include continued management of and support for the Accelerating Medicines Partnership in Rheumatoid Arthritis and Lupus. This effort, begun in 2014, is part of an innovative partnership among NIH, pharmaceutical companies, and nonprofit organizations to develop innovative models for identifying and validating promising biological targets for drug development. Researchers funded through the program will integrate data from multiple genome-wide analytic approaches to generate a comprehensive understanding of the mechanisms of tissue damage in rheumatoid arthritis and lupus. Such knowledge is essential for the development of new targeted therapies and for the application of existing and future therapies to appropriate patient populations. Other plans include supporting new and existing Resource-based Centers that provide critical infrastructure, facilities, and services to rheumatic disease investigators to improve the efficiency of their research programs. The Institute also will continue to support a clinical trial to compare the effects of two rheumatoid arthritis drugs on vascular inflammation, which is thought to be associated with the increased heart attack risk seen in people who have rheumatoid arthritis, as well as the joint inflammation for which these drugs are commonly prescribed.

Musculoskeletal Biology and Diseases: This program focuses on understanding the fundamental biology of tissues that constitute the musculoskeletal system and on translating and applying this knowledge to a variety of diseases and conditions, including osteoarthritis and chronic back and neck pain, and to recovery from injuries (see Program Portrait). For example, researchers are beginning to understand the genes that are activated after shoulder injuries and

² <http://www.cdc.gov/arthritis/basics/lupus.htm>

why rotator cuff muscles develop streaks of fat instead of healing. Others recently developed a mouse model that will allow researchers to study the molecular events that are responsible for healing of tendon to bone following a rotator cuff injury and possibly design pharmacologic or cell-based therapies for rotator cuff and other tendon injuries. In addition, the Osteoarthritis Initiative, a public-private partnership begun more than a decade ago, continues to encourage researchers to utilize the assembled big data resource to identify biomarkers that can predict structural and symptom changes.

Portrait of a Program: Clinical Orthopaedics Research

FY 2016 level: \$18.3 million

FY 2017 level: \$18.3 million

Change: \$0.0 million

NIAMS supports several clinical studies comparing how patients fare after different surgical and non-surgical treatments of chronic joint injuries, such as low back pain or acute trauma (e.g., knee injuries). The Spine Patient Outcomes Research Trial (SPORT), which has been comparing surgery and non-surgical treatment for the three most common causes of severe low back pain, has shown patients who have surgery initially do better than many who have other, non-operative treatments. The benefits of surgery remain up to eight years post-surgery for those patients who have a herniated lumbar disc, but differences between the people who had surgical or non-surgical treatments for spinal stenosis decrease with time. A complementary study looking at oral steroids as a non-operative treatment for lumbar disc herniation determined that people who had a short course of steroids gained only a modest improvement in function and no reduction of pain, compared with those who received a placebo. Other recent data from a group studying a specific physical therapy strategy support SPORT's conclusion that people with lumbar spinal stenosis who choose to delay or avoid surgery are not causing further damage (as long as their condition is not worsening). Furthermore, when combined with the SPORT findings that the benefits of surgery for this condition fade over several years, their results strongly suggest that most people who have lumbar spinal stenosis should try a standardized physical therapy regimen before considering surgery. Other investigators are studying surgical approaches for repairing knee injuries. Many participants in the Multicenter Orthopaedic Outcomes Network had torn their anterior cruciate ligament and also injured the meniscus that cushions the knee joint. New data show that repairing both injuries during a single surgery has long-term benefit; less than one-fifth needed a second operation because their initial meniscal repair "failed." This finding supports the value of meniscal repair over partial or complete removal – a treatment option that has increasingly become associated with the development of osteoarthritis.

Budget Policy:

The FY 2017 budget estimate for this program is \$144.862 million, the same as the FY 2016 Enacted level. In FY 2017, the program plans to encourage research into the degenerative changes that occur in the intervertebral discs (the gelatinous tissue that acts as shock absorbers between the bones of the spine) and the connection between these biochemical and biomechanical changes and chronic neck and back pain. This new effort was guided by a roundtable discussion that the Institute held in FY 2015 as part of its annual planning process. NIAMS will continue to support research into behavioral approaches to speed recovery following surgery. Other efforts may emerge from a planned FY 2016 discussion between members of the research community and NIAMS leadership about the Institute's musculoskeletal rehabilitation research portfolio.

Bone Biology and Diseases: This program covers a broad spectrum of research to better understand genetic and cellular mechanisms involved in the build-up and breakdown of bone. It supports studies of the molecular processes that regulate bone formation, bone resorption, and

mineralization, including the effects of hormones, growth factors, and other signals on bone cells. Other investigators are pursuing clinical studies that may lead to new or improved approaches for diagnosing bone diseases or treating patients. For example, building on knowledge that the presence and size of small tunnels or holes in the smooth outer surface of bone, its so-called porosity, are associated with a bone's strength and other biomechanical properties, investigators recently developed a method to measure porosity and related structural differences. The new approach takes a relatively short exam (compared with the time needed for other imaging approaches) and does not require exposure to ionizing radiation. Because it allows investigators to assess changes in pore size and pore number, the approach could lead to a more precise understanding of medications' effects and more targeted use of treatments. In another recent study, the drug paricalcitol, which is used to lower elevated parathyroid hormone levels (hyperparathyroidism) in people who have chronic kidney disease, was found to manage hyperparathyroidism in people who have a rare bone disease called X-linked hypophosphatemia (XLH). Because the drug inhibits parathyroid hormone, which is thought to be responsible for some of the XLH symptoms, it may be better for patients than current XLH treatments.

Budget Policy:

The FY 2017 budget estimate for this program is \$64.496 million, the same as the FY 2016 Enacted level. Program plans for FY 2017 include continuing to support the Brittle Bone Disorders Rare Disease Clinical Research Consortium, a component of the National Center for Advancing Translational Sciences' Rare Diseases Clinical Research Network that NIAMS co-funds with the National Institute of Dental and Craniofacial Research and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. NIAMS will partner with the Centers for Disease Control and Prevention to enable collection of bone mineral density data by the National Health and Nutrition Examination Survey (NHANES) to support the Healthy People 2020 bone health goals. NIAMS also will promote collaborations and the exchange of information at the agency level through the Federal Working Group on Bone Diseases—an interagency committee led by the Institute.

Muscle Biology and Diseases: This program supports a wide range of basic, translational, and clinical research projects in skeletal muscle biology and diseases. It focuses on the fundamental biology of muscle development, physiology, and muscle imaging. The overarching objective is to advance the understanding of the role that muscle plays in musculoskeletal and whole body health and, ultimately, to treat or prevent skeletal muscle diseases and disorders, including the muscular dystrophies, inflammatory myopathies, muscle ion channel diseases, disuse atrophy, skeletal muscle injury, and loss of muscle mass associated with aging and diseases. For example, two independent groups of investigators recently demonstrated that dysregulation of certain proteins involved in inflammation impairs muscle tissue regeneration. However, they also showed that interfering with these molecules may be a way to treat muscle wasting and disease - a finding that is particularly encouraging because drugs that target these molecules have been FDA-approved for other conditions. Another group of NIAMS-funded investigators, who originally were developing a mouse model for the neurodegenerative disease mucopolidosis, discovered a pathway that researchers might be able to manipulate for the treatment of the muscular dystrophies. Unlike many other treatment strategies, this approach would harness the ability of cells to repair the membrane tears that lead to muscle cell death. Other investigators,

building on recent discoveries about the molecular defects that cause facioscapulohumeral muscular dystrophy (FSHD), produced the first mouse model that can be used to study FSHD disease mechanisms and to test potential therapies.

Budget Policy:

The FY 2017 budget estimate for this program is \$67.863 million, the same as the FY 2016 Enacted level. Program plans for FY 2017 include continued participation in the Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers program, collaborations with other NIH components and Federal agencies to advance research objectives in the FY 2016 Action Plan for the Muscular Dystrophies, and efforts to encourage researchers to investigate the molecular processes by which skeletal muscle influences other organ systems. Other FY 2017 activities include ongoing support for institutional research training programs that will teach physicians and scientists how to incorporate genome-enabled and translational research approaches into their studies of healthy and diseased muscle tissue, provide post-doctoral exercise scientists and rehabilitation specialists with a training experience that integrates innovative basic research with clinical applications, and encourage pre- and post-doctoral muscle scientists to incorporate the development and testing of potential therapies into their research.

Skin Biology and Diseases: This program's support for basic, translational, and clinical research includes work on the developmental and molecular biology of skin, the skin as an immune organ, and the genetics of skin diseases. As researchers continue to explore the biological basis of skin's sensory functions, they are discovering molecular pathways that are involved in chronic itch, a symptom associated with many skin diseases and with responses to certain drugs. For example, scientists now have an explanation for why scratching an itch brings short-lived relief but often makes the itching worse in the long-term. They discovered that serotonin, a molecule released by the brain in response to pain (such as the mild soreness caused by scratching), intensifies itch in mice. They also identified the receptor protein that relays the serotonin-mediated itch signal. Subsequent studies in mice suggested that interfering with this receptor could be an effective approach to halting the often-debilitating itch that characterizes chronic conditions like psoriasis and eczema. Other investigators are exploring how fat cells protect skin from bacterial infections. Such findings may have implications for new treatments against *Staphylococcus aureus* (SA), a major cause of skin infections in humans, and Community-Associated Methicillin-Resistant *Staphylococcus Aureus* (CA-MRSA), an antibiotic resistant form of SA that presents a considerable public health challenge. In the area of genetic skin diseases, two research teams recently described independent cell-based approaches for treating the rare, painful, and sometimes fatal disease epidermolysis bullosa (EB). Both made skin grafts from a patient's own cells. Thus far, the human grafts have been tested in mice only, but they represent an important step toward developing personalized therapies that could help patients with EB and possibly other genetic diseases.

Budget Policy:

The FY 2017 budget estimate for this program is \$75.183 million, the same as the FY 2016 Enacted level. Program plans for FY 2017 include encouraging researchers to develop complex, three dimensional cell-based models of human skin tissue that investigators can use to study normal biology or disease, or for drug screening. Patient-specific models could be generated to study rare diseases or diseases where animal models are not available. This effort, which will be

targeted toward members of the small business community, builds on a roundtable discussion that the Institute held in FY 2015 as part of its annual planning process. NIAMS also will support the development and testing of strategies that can block the molecular pathways contributing to psoriasis and atopic dermatitis. For example, the Institute will continue funding a placebo-controlled clinical trial of an antibody that is thought to be safer and perhaps more effective than the broad immune suppressants that currently are prescribed for people who have moderate-to-severe atopic dermatitis.

Intramural Research Program: IRP conducts innovative basic, translational, and clinical research relevant to the NIAMS mission and trains investigators who are interested in related research careers. Its basic and physician-scientists study the genetics, etiology, pathogenesis, and treatment of rheumatic, autoimmune, inflammatory, bone, skin, and muscle diseases. They also partner with extramural clinical research networks in order to expand the reach of intramural clinical expertise around the nation. For example, faculty from the Vasculitis Translational Research Program participate in the Rare Diseases Clinical Research Network as part of the Vasculitis Clinical Research Consortium. This collaboration led to the recent discovery of a potential biomarker for predicting which patients with a disease known as ANCA-associated vasculitis are more likely to respond to treatment. The identification of biomarkers and novel therapeutic targets could help determine an individual's treatment response and lead to more personalized medical decisions. Other IRP investigators are developing strategies to help researchers and health care providers better assess the extent to which a disease affects a person or how well a patient is responding to treatment. Because diseases often impact several aspects of health that are important to patients (e.g., pain, function, fatigue, depression), investigators were interested in whether specific questions about how a person's health has changed were better than a single global question for estimating clinically important differences over the course of a study. Their findings show that six individual questions are more informative than a single standard question, despite the potential additional time and resources that the more extensive survey may require. Additional clinical research activities are described below (see Program Portrait).

Portrait of a Program: Clinical Research in the NIAMS Intramural Research Program (IRP)

FY 2016 level: \$21.4 million

FY 2017 level: \$21.4 million

Change: \$0.0 million

Many labs in IRP are engaged in clinical research studies to better understand rheumatic diseases (such as arthritis, periodic fever syndromes, lupus, myositis, and vasculitis) and to test interventions to improve outcomes for affected individuals. These programs have made significant advances for patients, including the identification and characterization of rare autoinflammatory diseases that are caused by genetic defects, and the clinical testing of existing drugs that could be repurposed for these patients. One of these drugs (anakinra) received FDA approval in 2013 for the new indication, creating an opportunity for it to be used for other rare childhood diseases.

NIAMS researchers continue to apply this expertise to other conditions. In addition to the vasculitis research noted above, the Vasculitis Translational Research Program has been working with colleagues in the Vasculitis Clinical Research Consortium to disseminate information about a new vasculitis-related clinical research opportunity at the NIH Clinical Center. The goals of the study include understanding what causes vasculitis, identifying new biomarkers to guide treatments, and using imaging techniques to examine blood vessels affected by the disease.

Recent additions to the IRP faculty have facilitated an expansion of clinical research studies for lupus patients. In addition to following individuals with lupus over time to better understand disease processes, two new interventional studies were initiated in FY 2015. One study is examining whether a common medication for diabetes can improve blood vessel function and reduce inflammation in people with lupus. A second study will explore the safety and tolerability of omalizumab, a drug approved to treat severe allergic asthma, in patients with mild to moderate lupus activity.

Budget Policy:

The FY 2017 budget estimate for this program is \$56.294 million, the same as the FY 2016 Enacted level. Program plans for FY 2017 include continuing to enhance the patient-oriented research component of the IRP portfolio (see Program Portrait) and to support the translation of observations regarding the genetic, inflammatory, and immune underpinnings of disease into clinical studies, and the use of clinical findings to inform mechanistic studies. The program's long-standing support for multidisciplinary training of rheumatology research fellows will continue as part of an Institute-wide commitment to strengthen the pipeline of highly qualified physician-scientists. NIAMS is also continuing participation in an NIH Funding Opportunity Announcement to promote collaborations between intramural and extramural investigators in order to leverage the unique research opportunities and resources available at the NIH Clinical Center.

Research Management and Support (RMS): The RMS budget supports the scientific, administrative management, and information technology activities associated with the NIAMS' day-to-day operations. In FY 2015, NIAMS managed more than 1,199 research grants and centers, as well as 45 research and development contracts and 286 individual and institutional full-time research training positions. NIAMS supported 541 clinical research studies, including 67 clinical trials. NIAMS is committed to making health information accessible to people from underserved racial and ethnic communities and to providing culturally and linguistically appropriate health information for diverse populations. In FY 2015, in order to meet an increasing demand for Spanish-language resources, NIAMS launched a Spanish-language portal on the NIAMS website. This section of the website features quick and easy navigation tools to help people who speak Spanish access health information and learn about clinical studies that they might be interested in. In addition, NIAMS is improving the digital accessibility of information for American Indians and Alaska Natives. On behalf of NIH, the NIAMS has partnered with the Indian Health Service and the Administration for Community Living's Administration on Aging to distribute a quarterly e-newsletter titled Honoring Health: Resources for American Indians and Alaska Natives. NIAMS also is continuing efforts to improve access to meaningful health information for racial and ethnic minority populations by developing and distributing health planners and other information for African American, Asian American, Pacific Islander, and Native Hawaiian, as well as Alaska Native, American Indian, and Spanish-speaking or bilingual Hispanic and Latino communities.

Budget Policy:

The FY 2017 budget estimate for this program is \$29.913 million, the same as the FY 2016 Enacted level. In FY 2017, NIAMS will continue to support the trans-NIH Language Access Plan initiative, an NIH-wide effort to make health information more accessible to people from underserved communities. As part of the Institute's commitment to the effort, more than 40 of the Institute's health education publications have now been translated and made available in

Chinese, Korean and Vietnamese; others are scheduled to be added over the next year. NIAMS is also implementing a new, automated system for integrating information about major research initiatives and health resources across the Institute's public web pages. The new infrastructure will provide all audiences with a comprehensive view of the work the NIAMS is doing, better communicate its public health mission, and improve performance for the Institute's internal needs.

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Budget Authority by Object Class¹
(Dollars in Thousands)

	FY 2016 Enacted	FY 2017 President's Budget²	FY 2017 +/- FY 2016
Total compensable workyears:			
Full-time employment	239	239	0
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary	\$184	\$185	\$1
Average GM/GS grade	12.5	12.5	0.0
Average GM/GS salary	\$103	\$103	\$0
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$0	\$0	\$0
Average salary of ungraded positions	\$0	\$0	\$0
OBJECT CLASSES	FY 2016 Enacted	FY 2017 President's Budget²	FY 2017 +/- FY 2016
Personnel Compensation			
11.1 Full-Time Permanent	\$14,877	\$14,990	\$113
11.3 Other Than Full-Time Permanent	10,311	10,389	79
11.5 Other Personnel Compensation	678	683	5
11.7 Military Personnel	315	318	2
11.8 Special Personnel Services Payments	2,414	2,432	18
11.9 Subtotal Personnel Compensation	\$28,595	\$28,813	\$218
12.1 Civilian Personnel Benefits	\$8,187	\$8,349	\$162
12.2 Military Personnel Benefits	246	248	2
13.0 Benefits to Former Personnel	0	0	0
Subtotal Pay Costs	\$37,028	\$37,410	\$382
21.0 Travel & Transportation of Persons	\$655	\$620	-\$35
22.0 Transportation of Things	91	90	-1
23.1 Rental Payments to GSA	17	17	0
23.2 Rental Payments to Others	0	0	0
23.3 Communications, Utilities & Misc. Charges	597	591	-6
24.0 Printing & Reproduction	0	0	0
25.1 Consulting Services	\$397	\$368	-\$30
25.2 Other Services	4,541	4,092	-450
25.3 Purchase of goods and services from government accounts	51,694	53,207	1,513
25.4 Operation & Maintenance of Facilities	\$7	\$7	\$0
25.5 R&D Contracts	3,613	2,685	-928
25.6 Medical Care	4,769	4,704	-65
25.7 Operation & Maintenance of Equipment	1,261	1,181	-80
25.8 Subsistence & Support of Persons	0	0	0
25.0 Subtotal Other Contractual Services	\$66,284	\$66,244	-\$39
26.0 Supplies & Materials	\$4,643	\$4,345	-\$298
31.0 Equipment	1,103	1,100	-3
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	431,244	431,244	0
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	0	0	0
44.0 Refunds	0	0	0
Subtotal Non-Pay Costs	\$504,634	\$504,252	-\$382
Total Budget Authority by Object Class	\$541,662	\$541,662	\$0

¹ Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

² Includes mandatory financing.

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Salaries and Expenses

(Dollars in Thousands)

OBJECT CLASSES	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Personnel Compensation			
Full-Time Permanent (11.1)	\$14,877	\$14,990	\$113
Other Than Full-Time Permanent (11.3)	10,311	10,389	79
Other Personnel Compensation (11.5)	678	683	5
Military Personnel (11.7)	315	318	2
Special Personnel Services Payments (11.8)	2,414	2,432	18
Subtotal Personnel Compensation (11.9)	\$28,595	\$28,813	\$218
Civilian Personnel Benefits (12.1)	\$8,187	\$8,349	\$162
Military Personnel Benefits (12.2)	246	248	2
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	\$37,028	\$37,410	\$382
Travel & Transportation of Persons (21.0)	\$655	\$620	-\$35
Transportation of Things (22.0)	91	90	-1
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	597	591	-6
Printing & Reproduction (24.0)	0	0	0
Other Contractual Services:			
Consultant Services (25.1)	65	64	-1
Other Services (25.2)	4,541	4,092	-450
Purchases from government accounts (25.3)	37,005	35,765	-1,240
Operation & Maintenance of Facilities (25.4)	7	7	0
Operation & Maintenance of Equipment (25.7)	1,261	1,181	-80
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$42,879	\$41,109	-\$1,770
Supplies & Materials (26.0)	\$4,643	\$4,345	-\$298
Subtotal Non-Pay Costs	\$48,865	\$46,755	-\$2,110
Total Administrative Costs	\$85,894	\$84,166	-\$1,728

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2015 Actual			FY 2016 Est.			FY 2017 Est.		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Intramural Research Program									
Direct:	128	1	129	129	1	130	129	1	130
Reimbursable:	6	-	6	6	-	6	6	-	6
Total:	134	1	135	135	1	136	135	1	136
Office of Extramural Activities									
Direct:	47	2	49	48	2	50	48	2	50
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	47	2	49	48	2	50	48	2	50
Office of the Director									
Direct:	53	-	53	53	-	53	53	-	53
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	53	-	53	53	-	53	53	-	53
Total	234	3	237	236	3	239	236	3	239
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0
FISCAL YEAR	Average GS Grade								
2013	11.8								
2014	11.6								
2015	12.5								
2016	12.5								
2017	12.5								

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Detail of Positions¹

GRADE	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	183,300	184,217	185,138
GM/GS-15	18	18	18
GM/GS-14	30	30	30
GM/GS-13	50	50	50
GS-12	22	24	24
GS-11	9	9	9
GS-10	0	0	0
GS-9	10	10	10
GS-8	5	5	5
GS-7	2	2	2
GS-6	3	3	3
GS-5	1	1	1
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	150	152	152
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	1	1	1
Senior Grade	0	0	0
Full Grade	3	3	3
Senior Assistant Grade	1	1	1
Assistant Grade	0	0	0
Subtotal	5	5	5
Ungraded	94	94	94
Total permanent positions	150	152	152
Total positions, end of year	248	250	250
Total full-time equivalent (FTE) employment, end of year	237	239	239
Average ES salary	183,300	184,217	185,138
Average GM/GS grade	12.5	12.5	12.5
Average GM/GS salary	102,174	102,511	103,024

¹ Includes FTEs whose payroll obligations are supported by the NIH Common Fund.